

**IN THE UNITED STATES COURT OF FEDERAL CLAIMS  
OFFICE OF SPECIAL MASTERS**

**No. 11-679V**

**Filed: April 13, 2012**

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AUDREY MCELROY,

Petitioner,

v.

SECRETARY OF HEALTH  
AND HUMAN SERVICES,

Respondent.

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Decision on the Record;  
Urticarial Vasculitis; Influenza

Donald Edwards, Atlanta, GA, for petitioner.  
Lara Englund, U.S. Dept. of Justice, Washington, DC, for respondent.

**RULING ON ENTITLEMENT<sup>1</sup>**

**Vowell**, Special Master:

On October 14, 2011, petitioner, Audrey McElroy, filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> [the “Vaccine Act” or “Program”]. The petition [“Pet.”] alleges she developed urticarial vasculitis as a result of an influenza [“flu”] vaccination she received on October 15, 2008. Pet. at ¶ 4. Based on the record a whole, I find sufficient evidence to issue a ruling in favor of entitlement.

**I. Procedural History.**

The petition, filed on October 14, 2011, was accompanied by six exhibits containing medical records. On November 2, 2011, petitioner filed the medical affidavit of Dr. Elise Brantley and supporting medical literature. A supplemental affidavit of Dr.

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<sup>1</sup> Because this unpublished ruling contains a reasoned explanation for the action in this case, I intend to post this decision on the United States Court of Federal Claims' website, in accordance with the E-Government Act of 2002, Pub. L. No. 107-347, 116 Stat. 2899, 2913 (Dec. 17, 2002). In accordance with Vaccine Rule 18(b), petitioner has 14 days to identify and move to delete medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will delete such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755 (1986). Hereinafter, for ease of citation, all “§” references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2006).

Brantley was submitted on December 30, 2011. Petitioner filed updated records from her primary care physician, as exhibit 9, on January 26, 2012.

On February 1, 2012, petitioner's statement of completion was filed and I ordered respondent to file her Rule 4(c) Report, along with her expert report, by no later than April 2, 2012. On April 2, 2012, respondent filed her Rule 4(c) report ["Report"]. The report concluded that "there is insufficient scientific evidence to support a causal relationship between influenza vaccine and vasculitis," and thus "compensation is not appropriate in this case." Report at 8. However, the report also indicated that "respondent will not expend further resources to contest entitlement in this matter" and recommended that "future proceedings be scheduled to determine the type and amount of compensation that should be awarded in this case with respect to petitioner's condition." *Id.* at 8-9.

## **II. Evidentiary Record.**

Audrey McElroy received her October 25, 2008 flu vaccine from her primary care physician Dr. R. Patrick Lucas, with Hawthorne Medical Associates-Athens ["HMA"]. Petitioner's Exhibit ["Pet. Ex."] 1, p.11. She had previously received flu vaccines in 2007 and 2006 from HMA. *Id.*, pp. 12, 26. She returned to HMA on November 6, 2008 with complaints of "a travelling urticaric rash on trunk and extremities for the past two weeks." Pet. Ex. 1, p. 9. She received injections of depromedrol and a prescription for Zyrtec. *Id.*, p. 10

On December 11, 2008, petitioner was seen at HMA with complaints of "erythematous 'welts' over entire trunk, extremities, scalp, and face 'hives.'" Pet. Ex. 1, p. 7. The onset of the rash was described as acute and occurring in a persistent pattern for 6 weeks. *Id.* Ms. McElroy reported itching associated with the rash, but indicated there had not been fevers. *Id.* Doctor Lucas noted that she had a flu shot a few days before, but concluded the timing was coincidental because "she has had the Flu shot numerous times before and the rash ha[d] lasted too long." *Id.*, p. 8. He believed she was having "some sort of allergic urticaria," and referred her to an allergist. *Id.*

On December 22, 2008, petitioner was examined by allergist Dr. Dean Firschein at Allergy Partners of Georgia. Ms. McElroy complained of a swollen right eyelid, numbness in her bottom lip, and an off and on fever of 101, in addition to continuing to suffer from hives. Pet. Ex. 3, p. 94.<sup>3</sup> Doctor Firschein noted that petitioner's flu shot "may have been a trigger or incidental event" but that "fever is usually not associated with allergies." *Id.*, p. 96. Given the duration of the hives, Dr. Firschein recommended some blood studies be done. *Id.*

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<sup>3</sup> I note that the exhibits containing petitioner's medical records were all consecutively numbered; page numbers were not restarted at page 1 with each new exhibit. The Guidelines for Practice indicate that each exhibit should be independently numbered. *Guidelines for Practice Under the National Vaccine Injury Compensation Program* at 7, <http://www.uscfc.uscourts.gov/sites/default/files/OSMGuidelines1104.pdf>.

Two weeks later, on January 5, 2009, petitioner returned to Allergy Partners of Georgia for a follow-up appointment. Doctor Firschein noted she had “chronic hives with no etiology” and indicated a possibility of them being stress induced or that she had “developed antibodies to FceReceptor.” Pet. Ex. 3, p. 93. At her follow-up appointment on February 23, 2009, petitioner reported that antihistamines were not helping, and that the hives got worse when she tried to stop taking xyzal, a prescription antihistamine.<sup>4</sup> Pet. Ex. 3, p. 98. Lab results reflected a high chronic urticaria (CU) index. *Id.*, pp. 98, 112.

On November 9, 2009, petitioner was seen by dermatologist Dr. David S. Lockman. He believed it was “highly likely” that petitioner had idiopathic urticaria, and did a biopsy for vasculitis. Pet. Exs. 2, p. 90; 1, p. 54. The biopsy uncovered “superficial, mid and deep dermal perivascular and vascular infiltrate extending to all surgical edges,” an indication of small vessel vasculitis. Pet. Ex. 2, p. 91. Petitioner returned to Dr. Lockman on December 4, 2009, and he indicated that she may have her urticaria long-term and would need to treat it with more than just antihistamines. Pet. Exs. 2, p. 89; 1, p. 54. He also recorded that petitioner was certain it started the same day as her flu vaccine. *Id.*

On December 17, 2009, Dr. Lockman stressed that finding the right therapy to manage petitioner’s urticaria will be a “trial and error type of situation.” Pet. Ex. 2, p. 87. His treatment notes from January 11, 2010, January 21, 2010, February 3, 2010, February 23, 2010, and March 12, 2010 reflect the struggle petitioner faced in finding the right treatment for her urticaria. *Id.*, pp. 81-86. Because the immunosuppressive therapies were causing infectious problems, Dr. Lockman noted that petitioner may “have a little IgG subclass,” and could consider IVIG treatment. *Id.*, p. 82.

Petitioner saw her primary care physician, Dr. Lucas, on January 12, 2010, for follow-up on her persistent pattern of skin problems, although no skin lesions were present on the day of the visit. Pet. Ex. 1, p. 3. Doctor Lucas noted that petitioner was referred by him to allergist Dr. Firschein, who in turn referred her to both a dermatologist, Dr. Lockman, and a rheumatologist, Dr. Teresa Lawrence. *Id.*, p. 4.

On March 10, 2010, petitioner was evaluated by Dr. Lawrence, with the North Georgia Rheumatology Group [“NGRC”], “to rule out any underlying Rheumatic disorders.” Pet. Ex. 6, p. 130. Doctor Lawrence ordered several laboratory tests. Pet. Ex. 6, pp. 132, 139-141. Petitioner returned to NGRC on April 30, 2010 to review her test results and evaluate her current symptoms. She had a low positive ANA with no evidence of systemic lupus erythematosus. Pet. Ex. 6, pp. 134, 139. Ms. McElroy stated she felt poorly, and that the skin lesions were getting worse. Pet. Ex. 6, p. 133. Doctor Lawrence proposed starting IVIG, but Ms. McElroy objected. *Id.*, p. 134. Additionally, Dr. Lawrence recommended petitioner obtain a second opinion from the Mayo Clinic. *Id.*

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<sup>4</sup> See <http://www.xyzal.com/default.aspx> (noting Xyzal consists of levocetirizine dihydrochloride); <http://www.ncbi.nlm.nih.gov/pubmedhealth/PMH0000405/> (identifying levocetirizine as an antihistamine).

Petitioner was evaluated again by Dr. Lawrence on June 29, 2010.<sup>5</sup> Doctor Lawrence noted that Ms. McElroy had “multiple tender trigger points in muscle groups characteristic of a fibromyalgia pattern.” Pet. Ex. 6, p. 137. Petitioner was assessed as having urticaria with vasculitis, although no evidence of systemic vasculitis was present, and probable secondary fibromyalgia syndrome. *Id.*

On January 6, 2011, Dr. Lucas noted that petitioner continued to have skin lesions and complained of scalp and leg pain. Pet. Ex. 9, p. 171. He recommended that Ms. McElroy see a rheumatologist with more experience in treating vasculitis. *Id.* On March 25, 2011, petitioner was evaluated by Dr. Elise Brantley at the Emory Dermatology Clinic. Doctor Brantley noted confusion in the history provided by Ms. McElroy regarding her current symptoms and the extent to which she continued to break-out in hives. Pet. Ex. 4, p. 124. On exam, Dr. Brantley noticed evidence of past lesions on her left arm. *Id.*, p. 125. Doctor Brantley confirmed petitioner’s diagnosis of urticarial vasculitis, and indicated that the “timing sounds like the flu shot could have been [the] trigger,” and included a citation to a case report regarding urticarial vasculitis secondary to a H1N1 vaccination. *Id.*

Doctor Brantley has additionally provided two affidavits, asserting that petitioner’s urticarial vasculitis was caused by her flu vaccine. The first affidavit was filed as exhibit 7 on November 2, 2011. A supplemental affidavit, which more fully addresses the relationship between petitioner’s flu vaccine and urticarial vasculitis, was filed as exhibit 8 on December 30, 2011.

### **III. Discussion.**

In order to prevail under the Program, petitioner must prove either a “Table” injury<sup>6</sup> or that a vaccine listed on the Vaccine Table was the cause-in-fact of an injury. Based on the record as a whole, petitioner has not established that she suffered a Table injury. She has, however, established that the flu vaccine she received on October 15, 2008, was the cause-in-fact of her vasculitis. See § 11(c)(1)(C)(i).

The Vaccine Act provides that a special master may not make a finding awarding compensation based on the claims of a petitioner alone, unsubstantiated by medical records or medical opinion. See § 13(a)(1). Petitioner has proffered both medical records and an expert medical opinion by Dr. Brantley causally linking her injuries to the flu vaccine.

To satisfy her burden of proving causation-in-fact, petitioner must “show by preponderant evidence that the vaccination brought about [his] injury by providing: (1) a

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<sup>5</sup> I note that in her rule 4(c) report, respondent identified this visit as occurring on August 29, 2010.

<sup>6</sup> A “Table” injury is an injury listed on the Vaccine Injury Table, 42 C.F.R. § 100.3, corresponding to the vaccine received within the time frame specified.

medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Althen v. Sec’y, HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005). See also, *Hines v. Sec’y, HHS*, 940 F.2d 1518, 1525 (Fed. Cir. 1991). She must show “that the vaccination was the reason for the injury. A reputable medical or scientific explanation must support this logical sequence of cause and effect.” *Grant v. Sec’y, HHS*, 956 F.2d 1144, 1148 (Fed. Cir. 1992). Circumstantial evidence and medical opinions may be sufficient to satisfy the second *Althen* factor. *Capizzano v. Sec’y, HHS*, 440 F.3d 1317, 1325 (Fed. Cir. 2006). Without more, “evidence showing an absence of other causes does not meet petitioner’s affirmative duty to show actual or legal causation.” *Grant, supra*, 956 F.2d at 1149. Mere temporal association is not sufficient to prove causation in fact. See *Hasler v. U.S.*, 718 F.2d 202, 205 (6<sup>th</sup> Cir. 1983), *cert. denied*, 469 U.S. 817 (1984).

When a petitioner alleges an “off-Table” injury, eligibility for compensation—the *prima facie* case—is established when the petitioner demonstrates, by a preponderance of the evidence, that: (1) she received a vaccine set forth on the Vaccine Injury Table; (2) that she received the vaccine in the United States; (3) that she sustained or had significantly aggravated an illness, disease, disability, or condition caused by the vaccine; and (4) that the condition has persisted for more than six months.<sup>7</sup>

According to the medical records, there is no dispute that Ms. McElroy received a covered vaccine administered in the United States. It is also clear that within a few days of receiving the flu vaccine, petitioner suffered from urticaria vasculitis which has persisted well beyond six months. Therefore, the only issue left to resolve is whether the flu vaccination administered on October 15, 2008, was the cause-in-fact of Ms. McElroy’s urticaria vasculitis.

In support of causation, petitioner offered Dr. Brantley’s medical affidavit. Doctor Brantley opined that Ms. McElroy’s “urticarial vasculitis most likely was caused by her flu vaccination, given the temporal association, as well as the documented evidence of previous flu vaccines causing similar eruptions in other patients in the literature.” Pet. Ex. 8 at 153. In reaching her opinion, Dr. Brantley acknowledged that the actual cause of urticarial vasculitis is unknown, but that it is believed that urticarial vasculitis is a “hypersensitivity syndrome.” *Id.* She explained that the flu vaccine acts as a trigger which initiates a hypersensitivity reaction,<sup>8</sup> which results in inflammation and the potential destruction of blood vessels. *Id.* In support of her opinion, Dr. Brantley cited

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<sup>7</sup> Section 13(a)(1)(A). This section provides that petitioner must demonstrate by a preponderance of the evidence the matters required in the petition by section 300aa-11(c)(1)....” Section 11(c)(1) contains the four factors listed above, along with others not relevant in this case.

<sup>8</sup> This reaction, which can be triggered by antigens or other events besides vaccinations, occurs when inflammatory markers and immune complexes become lodged in blood vessels’ walls, which then attracts inflammatory cells. The attraction of these cells in turn results in inflammation and potentially destruction of blood vessels. Pet. Ex. 8 at 153.

to several case reports in the medical literature discussing flu vaccines as the cause of vasculitis. See Pet. Exs. 8 at 155-158; 7 at 146-152.

Considering the only medical expert opinions offered<sup>9</sup> and the medical journal articles cited, I conclude that the weight of the evidence favors a causal connection between the flu vaccine and urticaria vasculitis in this case.

#### **IV. Conclusion.**

Petitioner has established the statutory requirements for entitlement. Based on the record before me, I find that there is preponderant evidence that petitioner's influenza vaccination was a substantial cause of her urticaria vasculitis. I further find that her urticaria vasculitis has persisted for more than six months.

**IT IS SO ORDERED.**

**s/Denise K. Vowell**

Denise K. Vowell  
Special Master

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<sup>9</sup> I note that respondent elected not to file a medical expert opinion.